UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,628	01/23/2004	Carter R. Anderson	20030304.ORI	7719

23595 7590 08/23/2007

NIKOLAI & MERSEREAU, P.A.
900 SECOND AVENUE SOUTH
SUITE 820
MINNEAPOLIS, MN 55402

EXAMINER	
SAMALA, JAGADISHWAR RAO	
ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
08/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/763,628	ANDERSON ET AL.	
	Examiner	Art Unit	
	Jagadishwar R. Samala	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's arguments see page 9-12, filed on May 24, 2007 with respect to the rejection (s) of claims 10, 11, 15-19 and 23-24 under 103 (a) have been fully considered but they are not persuasive. Therefore, the rejection (s) is maintained. However, upon further consideration, a new ground (s) of rejection is made in view of changes made in to the scope of the claims.

New ground (s) of rejection is prepared as follow:

Claims Disposition

2. Claims 10-24 are pending and present for examination.

Information Disclosure Statement (IDS)

3. Information Disclosure Statements filed on 04/29/2004, 12/12/2005 and 01/17/2006 have been received and entered. The reference cited on the PTO-1449 Form have been considered by the examiner and a copy is attached to the instant Office Action.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 10, 11, 15-19, 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sackler (US 2003/0068392 A1) in view of Stanley et al. (US 6,261,595 B1).

Applicant's arguments filed on May 24, 2007 have been fully considered but they are not persuasive.

Applicant's asserts that the Sackler reference does not teach a transdermal administration or prevention of abuse in transdermal devices for administering opioid analgesics.

Response:

First, claim 10 is drawn to a product (i.e. transdermal patch) and not a process claim.

Second, Sackler does teach a transdermal patch comprising an opoid agonist contained in a reservoir or a matrix, and an adhesive which allows the transdermal device to adhere to the skin, allowing the passage of the active agent from the transdermal device through the skin of the patient, with the inclusion of the aversive agents (e.g. the reservoir contains an aqueous gel comprising up to about 47-95% ethanol, 1-10% gelling agent, 0.1-10% buprenorphine, and release rate controlling means disposed in the flow path of the drug to the skin which limits the flux of the buprenorphine from the system through the skin, see para 0187). And further, inherently

all transdermal patches used will contain some residual amount of drug is retained in the patch after delivery of the active ingredient over a period of time and finally the entire device is discarded or disposed with anti-abuse substance. If the prior art structure is capable of performing the function of the instant delivery of an abusable substance to a patient, it meets the claims.

Applicant's assert that the Stanley reference is not related to prevention of abuse from residual amounts of delivered drugs.

Response:

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See In re Fine, 837 F.2d. 1071, 5 USPQ2d 1596 (Fed.Cir. 1988) and In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case Stanley teaches a transdermal drug delivery system comprising a dermal drug delivery patch and a heatin element pouch securable to the dermal drug delivery patch. And in claim 10, the word "comprising" is used. This term is open-ended language and transdermal patch taught by Stanley reads on the claim.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 10, 11, 15-19, 23 and 24 rejected under 35 U.S.C. 103(a) as being unpatentable over over Sackler (US 2003/0068392 A1) or Gale et al. (US 4,588,580) in view of Stanley et al. (S 6,261,596 B1) and Lee et al. (US 5,236,714).

Sackler meets the claim limitations as described above.

Gale teaches a transdermal delivery systems for delvery of fentanyl or its derivatives at a substantially constant rate for an extended period of time to produce analgesia (see abstract). And also discloses a transdermal delivery system 1 comprising a pouch formed from an impermeable backing 2, a rate controlling membrane 3, and an amine resistant contact adhesive layer 4, covered by a strippable protective backing 5. The impermeable backing 2 is configured to provide a central volume which contains a drug reservoir in the form a gel having dissolved and suspended drug therein (see col.5, lines 1-15). Inherently, the rate controlling membrane 3, could serve as closure means for closing said container as recited in the claim.

Lee teaches transdermal delivery device comprising a drug reservoir composition 11 typically in the form of a gel or polymeric carrier 12 having uniformly dispersed there through an abusable therapeutic agent 13 and an abuse negating amount of an antagonist therefor 14. The composition 11 is preferably disposed between an impermeable backing 15, an abusable substance releasing means such as release rate controlling membrane 16 and an abusable substance permeable adhesive 17. (see col.

5, lines 1-20). Inherently, the rate controlling membrane 16 could serve as closure means for closing the said container as recited in the instant claim.

Sackler, Gale and Lee references although teaches a transdermal delivery system or patch of an abusable substance in combination with an amount of antagonist for said abusable substance sufficient to substantially negate the pharmacological effect of the abusable substance or the transderaml device would administer the abusable substance through the skin at the rate intended for therapeutic effect, and the antagonist would not significantly affect or diminish the therapeutic effect of the abusable substance, fails to teach explicitly a closure means for closing the container or pouch, so that the container can also provide a closed system for disposing of the used skin-worm patch.

However it is well known in the art that transdermal patches as well as all medicine containing formulas are protected or enclosure in a container. As evidence by the 'Stanely patent teaching a transdermal drug delivery system comprising a dermal drug delivery patch and a heating element pouch securable to the dermal drug delivery patch (see abstract). Although the closure means for closing the container and also aiding in disposing of skin-worn patch as required by instant claim 10, as not been explicitly mentioned, because the pouch of the transdermal drug delivery patch taught by Stanely assist in the achievement of desired functional activity of transdermal patch, so that the container or pouch can also serve as a closed system for disposing of the used skin-worn patch.

It would have been obvious to one of ordinary skill in the art to modify the transdermal delivery system or patch disclosed by Sackler or Gale or Lee, to include a transdermal drug delivery system comprising a dermal drug delivery patch and a pouch closure means as an additional component for disposing of the used skin-worn patch. One of ordinary skill in the art would have been motivated to include the pouch or compartment in the transdermal dosage form disclosed by Sackler or Gale or Lee, because the teaching of Stanely while having a similar effect for drug delivery such as fentanyl, provide an additional and separate advantage as compared to the transdermal delivery system or patch disclosed by Sackler or Gale or Lee.

7. Claims 12-14 and 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sackler (US 2003/0068392 A1) or Gale et al. (US 4,588,580) or Lee et al. (US 5,236,714) in view of Schlendorfer et al. (US 5,899,856).

Sackler, Gale and Lee references although teaches a transdermal delivery system or patch of an abusable substance in combination with an amount of antagonist for said abusable substance sufficient to substantially negate the pharmacological effect of the abusable substance or the transderaml device would administer the abusable substance through the skin at the rate intended for therapeutic effect, and the antagonist would not significantly affect or diminish the therapeutic effect of the abusable substance, fails to teach explicitly to include activated charcoal as an anti-abuse substance.

However, a charcoal-containing binding or adsorption pad in a dermal patch to be worn on the skin is well known in the art as shown by '856.

The '856 patent teaches a transdermal patch that includes a charcoal containing adsorption pad for collecting vapor phase perspiration from a subject's skin and retaining a vapor phase analyte (see column 4, lines 37-44). And also, discloses dermal patches have included activated charcoal as a binding material. And also, discloses a transdermal patch that includes a charcoal—containing binding reservoir in an airtight adhesive cover for monitoring exposure to chemical substance. And further, carbon-containing wound dressings are well known (e.g. KALTOCARB i.e. Britcair, made of alginate and charcoal; OPRASORB (Lohmann GmbH & Co, KG, Nuweid, Germany), an activated charcoal cloth; and so (see col. 3, lines 12-45).

As claims are drawn to a composition, and inherently, the composition advanced by Sackler, Gale, and Lee in view of Schlendorfer would provide activated charcoal as anti-abuse substance. Since the essential elements of the cited references are identical to the instant invention (i.e., transdermal patch, antagonist, activated charcoal and further provide a transdermal delivery system of an abusable substance having a low potential abuse), the composition would inherently have the same physiochemical properties as the composition set forth in the instant application.

It would have been obvious to one of ordinary skill in the art to modify the transdermal dosage form of an abusable substance disclosed by Sackler, Gale, and Lee to include activated charcoal as an additional anti-abuse substance because Schlendorfer teaches that activated charcoal are useful for collecting vapor phase perspiration from a subject's skin because it provide the advantage for determining the presence of an analyte in perspiration of a subject mammal. One of ordinary skill in the

art would have been motivated to include the activated charcoal as an additional anti-abuse substance in the transdermal delivery system or patch disclosed by Sackler, Gale or Lee. It is well documented in the prior art the use of activated charcoal as a binding material. For e.g. (US 4,732,153) discloses a transdermal dossier to monitor exposure to chemical agents by providing an unbroken fluid link between tissue fluids in the skin and the fluid collecting component which may include activated charcoal as a binding material; (US 4,909,256) discloses a transdermal patch that includes a charcoal-containing binding reservoir in an airtight adhesive cover for monitoring exposure to chemical substance; and (US 4,906,467) discloses an occlusive patch for collection of liquid transdermal substances in a wettable substance binding reservoir of activated charcoal powder immobilized in a gel matrix (see column 3, lines 12-40).

Conclusion

1. No claims are allowed at this time.

2. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jagadishwar R. Samala whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jagadishwar R Samala
Examiner
Art Unit 1618

Zohreh Fay
Priamry Examiner
Art Unit 1618

Zohreh Fay